

AMENDMENT

Listing of the Claims:

The following listing of claims replaces all previous listings or versions thereof:

1.-29. (Cancelled)

30. (Previously Presented) A recombinant adenovirus composition comprising between 5×10^{14} and 1×10^{18} viral particles and having less than 50 ng of BSA per 1×10^{12} viral particles.

31. (Previously Presented) The purified recombinant adenovirus composition of claim 30 or 41, said composition having between about 50 pg and 10 ng of contaminating human DNA per 1×10^{12} viral particles and one or more of the following properties:

- (a) a virus titer of between about 1×10^9 and about 1×10^{13} pfu/ml;
- (b) a virus particle concentration between about 1×10^{10} and about 2×10^{13} particles/ml;
- (c) a particle:pfu ratio between about 10 and about 60;
- (d) having less than 50 ng BSA per 1×10^{12} viral particles;
- (e) elutes essentially as a single peak upon HPLC.

32. (Previously presented) The composition of claim 30 or 41, wherein the composition has a viral titer of between about 1×10^{11} and about 1×10^{13} pfu/ml.

33. (Original) The composition of claim 32, wherein the composition has a viral titer of between about 1×10^{12} and about 1×10^{13} pfu/ml.

34. (Previously Presented) The composition of claim 30 or 41, wherein the composition has a virus particle concentration between about 1×10^{11} and about 2×10^{13} particles/ml.

35. (Previously Presented) The composition of claim 34, wherein the composition has a virus particle concentration between about 1×10^{12} and about 1×10^{13} particles/ml.

36. (Previously Presented) The composition of claim 30 or 41, wherein the composition has a particle:pfu ratio between about 10 and about 50.

37. (Original) The composition of claim 36, wherein the composition has a particle:pfu ratio between about 10 and about 40.

38. (Original) The composition of claim 37, wherein the composition has a particle:pfu ratio between about 20 and about 40.

39. (Previously Presented) The composition of claim 30 or 41, wherein the composition has between about 1 ng and 50 ng of BSA per 1×10^{12} viral particles.

40. (Original) The composition of claim 39, wherein the composition has between about 5 ng and 40 ng BSA per 1×10^{12} viral particles.

41. (Currently Amended) A purified recombinant adenovirus composition comprising between 5×10^{14} and 1×10^{18} adenoviral particles and between about 50 400 pg and 10 ng of contaminating human DNA per 1×10^{12} viral particles.

42. (Previously Presented) The composition of claim 30 or 41, wherein the composition has between about 100 pg and 500 pg of contaminating human DNA per 1×10^{12} viral particles.
43. (Original) The composition of claim 30 or 41, wherein the adenovirus of said composition elutes as essentially a single HPLC peak that comprises between 97 and 99% of the total area under the peak.
44. (Previously presented) The composition of claim 30 or 41, wherein the composition has between about 50 pg and about 7 ng of contaminating human DNA per 10×10^{12} viral particles.
45. (Previously presented) The composition of claim 44, wherein the composition has between about 50 pg and about 5 ng of contaminating human DNA per 1×10^{12} viral particles.
46. (Previously presented) The composition of claim 45, wherein the composition has between about 50 pg and about 3 ng of contaminating human DNA per 1×10^{12} viral particles.
47. (Previously presented) The composition of claim 46, wherein the composition has between about 50 pg and about 1 ng of contaminating human DNA per 1×10^{12} viral particles.
48. (Previously presented) The composition of claim 46, wherein the composition has between about 50 pg and about 500 pg of contaminating human DNA per 1×10^{12} viral particles.
49. (Previously presented) The composition of claim 31, wherein the composition has all of (a)-(e).

RESPONSE TO THE OFFICE ACTION

A. Status of the Claims

Claims 30-49 are currently pending in this application. Claim 41 has been amended.

Claim 30 has been allowed and claims 31-49 are under consideration.

B. Claims Are Enabled

Claims 31-49 are rejected under 35 U.S.C. §112 as failing to comply with the enablement requirement. The Examiner contends that the specification, "while being enabling for compositions with 0.4-10 ng of contaminating human DNA per 10^{12} virus particles, does not reasonably provide enablement for the lower range of 50 pg." Action, page 2. Applicants respectfully traverse.

Applicants have provided written description which indicates that the recombinant adenovirus composition of the present invention may possess low contaminating human DNA values such as 50 or 100 pg per 1×10^{12} viral particles. The working example shows an amount of human DNA contamination of 400 pg on page 169 of the specification. However, applicants contend this one illustration should not preclude enablement. However, Applicants hereby submit a copy of the Declaration of Joseph Senesac as previously submitted during prosecution of U.S. Patent Application Serial No. 09/556,570. This declaration indicates that human DNA contamination levels of less than 400 pg per 1×10^{12} have been achieved. As such, Applicants contend that claims 31-49 are enabled. Therefore, the Applicants respectfully request that the Examiner withdraw the rejections to claims 31-49.

C. CONCLUSION

It is submitted that in light of the foregoing amendments and remarks, the invention embraced by the pending claims as been shown to be patentable, and favorable reconsideration is earnestly solicited. Therefore, Applicants respectfully request that the Examiner withdraw each of the above rejections.

The Examiner is invited to contact the undersigned attorney at (512) 536-3081 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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